UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

R.M., Plaintiff V. ANTHEM BLUE CROSS AND BLUE SHIELD, THE CAPITAL ONE FINANCIAL CORPORATION EMPLOYEE BENEFITS PLAN, AND CAPITAL ONE FINANCIAL CORPORATION Defendants	CIVIL ACTION NO.

COMPLAINT

INTRODUCTION

1. Plaintiff, R.M. brings this action against the Defendants, Anthem Blue Cross and Blue Shield ("Anthem"), The Capital One Financial Corporation Employee Welfare Benefits Plan ("the Plan"), and Capital One Financial Corporation ("Capital One") (collectively referred to as "Defendants") for violations of the Employee Retirement Income Security Act of 1974, as amended, 29 U.S.C. §§ 1001 et. seq. ("ERISA"). R.M., a minor, was a beneficiary of an ERISA welfare benefit plan administered by Anthem and insured by Capital One.
2. Plaintiff challenges Defendants': 1) unreasonable and unlawful denial of R.M.'s claim for vertebral body tethering ("VBT") surgery to treat scoliosis despite substantial medical evidence demonstrating R.M.'s entitlement to said benefits; 2) pattern of rejecting and/or

ignoring the substantial evidence supporting R.M.'s entitlement to coverage; 3) failure to provide R.M. with a full and fair review of her claim; and 4) failure to provide a reasonable claims procedure that would yield a decision on the merits of R.M.'s claim.

JURISDICTION

3. This Court has personal and subject matter jurisdiction over this case under 29 U.S.C. § 1132(e) and (f), without regard to jurisdictional amount or diversity of citizenship, in that the Defendants' breach of their ERISA obligations took place in this district.

PARTIES

4. The plaintiff, R.M., presently resides in Tyngsboro, Massachusetts. At the time the treatment began which is the subject of this Complaint, R.M. was, and continues to be, a minor dependent beneficiary of a participant in the Plan, within the meaning of 29 U.S.C. § 1002(2)(7). R.M. has standing to bring this action under 29 U.S.C. § 1132(a).
5. The Defendant, Anthem, is a for-profit corporation, with its principal place of business at 220 Virginia Avenue, Indianapolis, IN 46204. Anthem was responsible for administering claims under the Plan and making decisions regarding Plan participants' eligibility for benefits.
6. The Defendant, the Plan, is an "employee welfare benefit plan" as defined by ERISA, 29 U.S.C. §1002(1).
7. The Defendant, Capital One, is a for-profit corporation, with its principal place of business at 1680 Capital One Drive McLean, VA 22102. Capital One is responsible for insuring claims made under the Plan.

8. At all times relevant to the claims asserted in this Complaint, Anthem and Capital One purported to act as an ERISA claims fiduciaries with respect to participants of the Plan generally, and specifically with respect to R.M., within the meaning of ERISA.

FACTS

The Plan.

9. As a dependent of a Plan employee, R.M. was entitled to health insurance coverage under the Plan.

10. For R.M.'s VBT to be a covered benefit under the Plan, it must be Medically Necessary, defined in the Plan as:

> - A service or supply furnished by a particular provider is necessary if Anthem determines that it is appropriate for the diagnosis, care or treatment of the disease or injury involved.
>
> To be appropriate, the service or supply must:
> - Be care or treatment as likely to produce a significant positive outcome, and no more likely to produce a negative outcome, than any alternative service or supply, both as to the disease or injury involved and the person's overall health condition;
> - Be a diagnostic procedure, indicated by the health status of the person and be as likely to result in information that could affect the course of treatment as, and no more likely to produce a negative outcome than, any alternative service or supply, both as to the disease or injury involved and the person's overall health condition; and
> - As to diagnosis, care and treatment be no more costly (taking into account all health expenses incurred in connection with the service or supply) than any alternative service or supply to meet the above tests.

11. The Plan excludes treatment it determines to be Experimental or Investigational from coverage, defined in the Plan as the following:

> Care is considered experimental or investigational if:
>
> - There are insufficient outcomes data available from controlled clinical trials published in the peer reviewed literature to substantiate its safety and effectiveness for the illness or injury involved; or
> - It does not have a required approval for marketing by the U.S. Food

and Drug Administration; or

- A nationally-recognized medical or dental society or regulatory agency has determined, in writing, that it is experimental, investigational or for research purposes; or
- It is a type of drug, device or treatment that is the subject of a Phase 1 or Phase II clinical trial or the experimental or research arm of a Phase III clinical trial, using the definition of "phases" indicated in regulations and other official actions and publications of the FDA and Department of Health and Human Services; or
- The written protocol(s) or written informed consent used by the treating facility—or another facility studying the same drug, device, treatment or procedure—states that it is experimental, investigational or for research purposes.

12. To determine whether the requested treatment is Medically Necessary, Anthem applied its Vertebral Body Stapling and Tethering for the Treatment of Scoliosis in Children and Adolescents Coverage Guidelines, which state:

> Vertebral body stapling and vertebral body tethering as treatment of scoliosis in children and adolescents are considered investigational and not medically necessary.

R.M.'s Claim for VBT and Anthem's Response.

13. R.M. suffers from severe progressive scoliosis, for which "surgical intervention was clearly indicated" as described by her treating surgeon Dr. Amer Samdani.

14. R.M.'s treating providers recommended she pursue VBT as traditional surgical intervention (spinal fusion) would drastically limit her spinal motion and over time lead to worse outcomes including degenerative disease of her spine, pain, and limited motion.

15. The VBT tethering device was approved by the Food and Drug Administration ("FDA") on August 16, 2019.

16. On March 4, 2020, Anthem denied R.M.'s claim for VBT as Investigational, based on Anthem's determination "[t]his procedure is not approvable under the plan clinical criteria because there is no proof or not enough proof that it improves health."

17. In making this determination, Anthem relied on its VBT Medical Policy.

18. On March 13, 2020, R.M.'s mother requested an expedited appeal of Anthem's denial, submitting a treatment narrative, peer reviewed article, and article regarding the FDA's approval of VBT.

19. On March 19, 2020, and again on April 19, 2020, Anthem upheld its decision to deny R.M.'s claim for VBT.

20. On May 4, 2020, R.M. submitted a request for her complete claim file to Anthem.

21. On May 15, 2020, R.M. timely submitted her second level appeal to Anthem.

22. Follow-up requests for R.M.'s claim file were forwarded to Anthem on May 14, 2020, June 3, 2020, June 17, 2020, July 1, 2020, July 24, 2020.

23. On July 29, 2020, Anthem provided R.M. with an incomplete copy of her claim file, 86 days after her initial request.

24. After multiple follow-up requests for the missing documentation in R.M.'s claim file, Anthem provided additional information to R.M. on August 21, 2020, September 1, 2020, and September 14, 2020. Each disclosure was incomplete.

25. On July 4, 2020, R.M. received an explanation of benefits ("EOB") from Anthem denying her claim for her surgical stay due to lack of prior authorization, even though the prior authorization request was submitted, and denied by Anthem on March 4, 2020 and was appealed by R.M. on May 15, 2020.

26. On September 1, 2020, R.M. timely filed her appeal of the July 4, 2020 EOB denial.

27. On October 30, 2020, R.M. supplemented her appeals with her complete medical and surgical records from two hospitals, two treatment narratives from her treating and

examining surgeons, an affidavit from her mother, and peer reviewed literature on the efficacy of VBT.

28. On November 6, 2020, R.M. requested the opportunity to respond to any medical reviews conducted on appeal prior to Anthem's conclusion of the internal appeals process.

29. R.M. submitted follow up requests for Anthem's medical reviews on November 23, 2020, December 14, 2020, and December 22, 2020.

30. On December 22, 2020, without providing R.M. the opportunity to review and respond to Anthem's medical reviews, Anthem upheld its denial of coverage.

31. Anthem's refusal to provide R.M. with a copy its medical reviews conducted on appeal constituted a violation of ERISA's implementing regulations and First Circuit precedent. *See Jette v. United of Omaha Life Ins. Co*., 18 F.4th 18 (1st Cir. 2021).

32. On May 7, 2021, R.M. submitted a request for reconsideration of Anthem's decision to Capital One.

33. On June 10, 2021, Capital One determined that R.M.'s claim was properly denied.

34. Neither Anthem nor any of the medical review opinions Anthem relied on addressed the substance of R.M.'s treating surgeon and independent examining surgeon's opinions regarding the medical necessity of her VBT surgery, which contradicted Anthem's medical reviewers' conclusions.

35. Neither Anthem nor any of the medical review opinions Anthem relied on addressed the FDA approval of VBT, which contradicted Anthem's medical reviewers' conclusions that the procedure is "investigational.," pursuant to its own definition of the exclusion.

36. Neither Anthem nor any of the medical review opinions Anthem relied on spoke with her treating or examining physicians, despite her surgeon's repeated calls to Anthem and her mother's multiple attempts to schedule a discussion with Anthem's physician.

37. None of the reviewers Anthem relied on to deny benefits examined R.M.

38. R.M. exhausted the internal appeals process provided by Anthem prior to filing suit.

Summary of Defendants' Review of R.M.'s Claim.

39. R.M. has exhausted her administrative remedies pursuant to 29 C.F.R. 2560.503-1(1).

40. R.M.'s eligibility for benefits is based on the substantial evidence in Defendants' possession.

41. The Defendants failed to respond to R.M.'s attempts to engage in a meaningful dialogue regarding the evaluation of her claim.

42. Any discretion to which the Defendants may claim they are entitled under the Plan is negated by their failure to provide R.M. with explanations as to their adverse decisions as proscribed by ERISA and its implementing regulations.

43. The Defendants failed to meet the minimum requirements for the denial of R.M.'s benefits, in violation of ERISA, 29 U.S.C. 1133, which requires that upon a denial of benefits, the administrative review procedure must include adequate notice in writing setting forth the specific reasons for the denial of benefits and a reasonable opportunity for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

44. The Defendants have also failed to meet the Plan requirements for review of claims that have been denied.

45. The Defendants failed to provide R.M. with a full and fair review of her claim for benefits.

46. On appeal, Anthem's physicians made no attempt to respond to or engage with R.M.'s physician's detailed treatment narratives addressing the elements of medical necessity, as that term is defined by the Plan.

47. The decision to deny R.M. benefits was self-serving, wrongful, unreasonable, irrational, solely contrary to the evidence, contrary to the terms of the Plan and contrary to law.

48. Due to the unlawful denials of benefits under ERISA, R.M. suffered significant financial loss.

49. Having exhausted the administrative procedures provided by the Defendants, R.M. now brings this action.

FIRST CAUSE OF ACTION
(Enforcement of Terms of Plan
Action for Unpaid Benefits)
(ALL DEFENDANTS)

50. R.M. realleges each of the paragraphs above as if fully set forth herein.

51. The Plan is a contract.

52. R.M. performed all her obligations under the contract.

53. In particular, R.M. met all of the conditions for the payment of health insurance benefits under Plan, including but not limited to, providing the Defendants proof of the medical necessity of the requested treatment services, pursuant to the terms of her insurance contract. Nonetheless, Defendants have failed to provide R.M. with the health insurance benefits he is due under the terms of the Plan.

54. 29 U.S.C. § 1132(a)(1)(B) states that:

> A civil action may be brought ---

1. by a participant or beneficiary –

    1. for the relief provided for in subsection (c) of this section, or

    2. to recover benefits due to her under the terms of her plan, to enforce her rights under the terms of the plan, or to clarify her rights to future benefits under the terms of the plan.

55. The Defendants' actions constitute an unlawful denial of benefits under ERISA, as provided in 29 U.S.C. §1132(a)(1)(B).

56. The Defendants unlawfully denied R.M.'s benefits in part by failing to provide R.M. with a full and fair review of their decision to deny coverage for her claim for VBT.

57. In accordance with 29 U.S.C. §1132, R.M. is entitled to coverage for the medical care R.M. received under the Plan based upon the medical necessity of this treatment.

58. The Defendants refused to provide R.M. with coverage for the covered medical services received, and are, therefore, in breach of the terms of the Plan and ERISA, which requires that the Defendants engage in a full and fair review of all claims and the administration of the Plan in the best interests of the Plan participants.

59. R.M. is entitled to the Massachusetts twelve percent statutory rate of interest due to the loss of the use of the funds expended to pay for R.M.'s medical necessity treatment.

SECOND CAUSE OF ACTION
(Attorney's Fees and Costs)
(ALL DEFENDANTS)

60. R.M. realleges each of the paragraphs above as if fully set forth herein.

61. Under the standards applicable to ERISA, R.M. deserves to recover "a reasonable attorney's fee and costs of the action" herein, pursuant to section 502(g)(1) of ERISA, 29 U.S.C. § 1132(g).

62. Defendants have the ability to satisfy the award.

63. R.M.'s conduct of this action is in the interests of all participants who subscribe to the Plan, and the relief granted hereunder will benefit all such participants.

64. The Defendants have acted in bad faith in denying R.M.'s health insurance benefits under the terms of the respective Plan.

65. The award of attorney's fees against the Defendant will deter others acting under similar circumstances.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff, R.M., requests this Court to:

(1) Enter judgment for R.M. against Defendants;

(2) Declare, adjudge, and decree that Defendants are obligated to pay R.M. the cost of the disputed services;

(3) Order that the Defendants make restitution to R.M. in the amount of all losses sustained by R.M. as a result of the wrongful conduct alleged herein, together with prejudgment interest;

(6) Award twelve percent interest, costs, and attorneys' fees to R.M.; and

(7) Award such other relief as this Court deems just and proper .

Date: December 21, 2021

Respectfully submitted,

R.M.

By her attorney,

/s/ Mala M. Rafik
Mala M. Rafik
BBO No. 638075
ROSENFELD & RAFIK
184 High Street, Suite 503
Boston, MA 02110
T: 617-723-7470
F: 617-227-2843
E: mmr@rosenfeld.com